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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,623	06/20/2003	Uri H. Saragovi	62950-010310	7195

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,623	SARAGOVI ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, as specifically drawn to a compound to selectively kill a target cell in a patient with reduced systemic toxicity, which comprises a compound of the formula:

W-Z-X

wherein, X is a therapeutic agent; W is a molecule that is adapted to selectively bind a target cell; and Z is a breakable linker, classified in class 530, subclass 391.7.
(Upon election of Group I, the applicant must choose ONE "therapeutic" agent from those listed in Claim 1 or 5 and ONE "molecule" from those listed in Claim 8, as each therapeutic agent and molecule is a distinct invention requiring separate searches, NOT a species)

II. Claims 26-29, as specifically drawn to a method of treating cancer, classified in class 424, subclass 181.1.
(Upon election of Group II, the applicant must choose ONE "therapeutic" agent from those listed in Claim 1 or 5 and ONE "molecule" from those listed in Claim 8, as each therapeutic agent and molecule is a distinct invention requiring separate searches, NOT a species)

III. Claim 30, as specifically drawn to a method for by-passing resistance of tumor cells by p-glycoprotein pump (PGP), classified in class 424, subclass 178.1.
(Upon election of Group III, the applicant must choose ONE "therapeutic" agent from those listed in Claim 1 or 5, as each therapeutic agent is a distinct invention requiring separate searches, NOT a species)

IV. Claims 31-33, as specifically drawn to a compound to selectively protect a target cell which comprises a compound of formula:

W-Z-X

wherein, X is a protective agent; W is a biologically active molecule; and Z is a linker which covalently links W and X together, classified in class 536, subclass 1.11.
(Upon election of Group IV, the applicant must choose ONE "protective" agent from those listed in Claim 31, as each protective agent is a distinct invention requiring separate searches, NOT a species)

V. Claim 34, as specifically drawn to a method for decreasing toxic effects to non-tumor cells, classified in class 514, subclass 168.
(Upon election of Group V, the applicant must choose ONE "protective" agent from those listed in Claim 31, as each protective agent is a distinct invention requiring separate searches, NOT a species)

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and IV are related by virtue of the fact that each comprises an "agent" which is linked to a molecule that is adapted to selectively bind to a target cell. However, the inventions of Groups I and IV represent separate and distinct products, which are comprised of materially/structurally different agents. Moreover, the product comprised of a therapeutic agent linked to a targeting molecule (Group I) and the product comprised of a protective agent linked to a targeting molecule (Group IV) are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For the product comprising a therapeutic agent, the product can be used for selectively killing a target cell. For the product comprising a protective agent, the product can be used to selectively protect a cell. Therefore, each product is divergent in materials and outcomes. For these reasons the inventions of Group I and IV are patentably distinct.

Furthermore, searching the inventions of Groups I and IV together would impose a serious search burden. In the instant case, the search of a product comprising a therapeutic agent such as paclitaxel or a protective agent is not coextensive. The inventions of Groups I and IV have a

separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and IV.

The inventions of Groups II-III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method of treating cancer (Group II), the method for by-passing resistance of tumor cells by p-glycoprotein pump (PGP) (Group III), and the method for decreasing toxic effects to non-tumor cells (Group V) are unrelated as the comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for treating cancer by selectively killing a target cell differ significantly for each of the materials. For selectively killing a target cell, either a therapeutic agent such as paclitaxel may be used or an antisense oligonucleotide. For decreasing the toxic effects to non-tumor cells, a protective agent such as Vitamin D may be used. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Group II-III and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II-III and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II-III and V.

The inventions of Group I and the method of Groups II-III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in a materially different process such as for either treating cancer or for by-passing resistance of tumor cells by p-glycoprotein pump (PGP).

Searching the inventions of Groups I-III together would impose serious search burden. The inventions of Groups I-III have a separate status in the art as shown by their classification.

Moreover, in the instant case, the search for the compound comprising a therapeutic agent linked to a molecule and the methods of treating cancer and by-passing resistance of tumor cells by p-glycoprotein pump (PGP) are not coextensive. Prior art which teaches a compound comprising a therapeutic agent linked to a targeting molecule would not necessarily be applicable to the method of using the compound. Moreover, even if the products were known, the method of treatment and/or the by-passing resistance of tumor cells that used either of the products may be novel and unobvious in view of the preamble or active steps.

The inventions Group IV and the method of Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound comprising a protective agent linked to a targeting molecule can be used in a materially different process other than for decreasing the toxic side effects such as for imagining, wherein the product is labeled and used to visualize tumor cells.

Searching the inventions of Groups IV-V together would impose serious search burden. The inventions of Groups IV-V have a separate status in the art as shown by their classification. Moreover, in the instant case, the search for the compound comprising a protective agent linked to a targeting molecule and the method of decreasing the toxic side effects to non-tumor cells are not coextensive. Prior art, which teaches a compound comprising a protective agent linked to a targeting molecule would not necessarily be applicable to the method of using the compound. Moreover, even if the product was known, the method of treatment that used the product may be novel and unobvious in view of the preamble or active steps.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER